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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,612	03/20/2001	Kanji Takada	AKA-269	4679

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,612	Applicant(s) TAKADA, KANJI	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- Th MAILING DATE of this communication appears on th cov r sh t with the correspond nc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-19* is/are pending in the application.

4a) Of the above claim(s) *20-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Extension of Time and Amendment B received July 23, 2002 are acknowledged. Claims 10-19 are included in the prosecution of this application. Claims 20-26 are withdrawn from consideration.

Election/Restrictions

Newly submitted claims 20-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Note if the product claims are deemed to be allowable during prosecution, the process claims may be subject to rejoinder.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant argues that JP 3-255037 teaches an enteric-coating that is dissolved and that ethylcellulose coating in Takada ruptures. Applicant argues that Sipos teaches an enteric coating for an enzyme composition that is capable of withstanding gastric

fluid and instant invention teaches ethlycellulose that ruptures selectively in the colon by peristalsis. Applicant argues that Masanobu does not teach a glyceride based composition nor suggest an ethylcellulose coating. It is argued that Masanobu teaches the encapsulation of a drug solution into gelatin capsules, whereas Takada teaches forming the capsule before including the drug.

Applicant's arguments have been fully considered but they are not persuasive. As recognized by the applicant, JP 3-255037 teaches an enteric coating. Webster's definition of enteric is: medicinal preparation treated to pass thorough the stomach unaltered and disintegrate in the intestines. The intended use of the enteric coating whether is dissolved or ruptured, does not hold patentable weight unless a structural difference in the end product is shown. Therefore, JP and Takada's products teach the same site-delivery. One of ordinary skill in the art would look to JP for the teachings of a glycyrrhizin preparation and Takada for the specific teachings of enteric delivery using an ethylcellulose coating.

The examiner relies on the Sipos to teach the conventional use of talc before coating a product and not the composition of the active itself. The examiner points out that Sipos is used as a secondary reference and for its specific teachings. The primary reference is used for the broad teaching of a glycyrrhizin preparation for enteric delivery. Additionally, the examiner points out that although Sipos teaches the enteric coating to withstand gastric fluids, the target site is the intestine hence the term enteric coating (abstract).

Lastly, the examiner points out that the recited claims are product claims and the method in which the product is made is not given patentable weight. Therefore, whether the capsule is formed before the inclusion of the drug or after is not considered as long as the end product is the same. Additionally, Masanobu is used as a secondary reference in an obviousness-type rejection and does not have to anticipate all the limitations.

*Note that amended claim 10 recites the new limitation of glyceride, therefore necessitating new rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-255037 in view of Takada (5,637,319).

JP 3-255037 teaches a glycyrrhizin preparation that increases the concentration of glycyrrhizin in the blood by preparing the drug with an enteric coating. This allows the drug to be absorbed by the small intestine and moved quickly to the blood. Further, glycyrrhizin is used for the therapy of liver disease and allergies.

JP does not teach an ethylcellulose enteric coating.

Takada teaches an oral controlled release preparation to deliver drugs to the lower gastrointestinal tract. The reference teaches the suitability of the dosage form for

drugs that need to be delivered to the lower part of the small intestine and/or colon (col. 3, lines 58-63). The dosage form allows for a sustained release and the gastrointestinal cells are exposed to high concentration of the drug (col. 3, lines 35-50). Takada teaches an ethyl cellulose covered capsule containing a drug composition (Fig. 9). The reference teaches that the thickness of the water soluble membrane and the intestinal pressure control the release of the material so that the delivery system is site specific and delivers the drug to the large intestine (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Takada's controlled release capsule with a polymer coating since Takada teaches the dosage form prevents the degradation of the active by the upper parts of the GI tract, it allows for a sustained-release of the active, and it is suitable for drugs that need to be delivered to lower small intestine.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-255037 in view of Takada (5,637,319) in further view of Sipos (4079125).

As set forth above, JP teaches a glycyrrhizin preparation and Takada teaches an ethylcellulose coated dosage form for delivery to the lower GI tract.

The references do not teach dusting the core with talc.

Sipos teaches an enteric coating for the delivery of drugs to the intestinal region. In the enteric coat method, Sipos teaches dusting talc on the tablet to prevent aggregation of the tablet (col. 8, line 65 to col. 9, line 4). Further, Sipos teaches enteric coating methods are well known in the art (col. 9, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dust the oral preparation with talc since this prevents aggregation of the tablet during the coating method as taught by Sipos.

Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-255037 in view of Takada (5,637,319) in further view of JP 10226650.

As set forth above, JP teaches a glycyrrhizin preparation and Takada teaches an ethylcellulose coated dosage form for delivery to the lower GI tract.

The references do not teach the inclusion of an additional absorption promoter.

Masanobu (JP 10226650) teaches an oral preparation containing glycyrrhizin and an absorption promoter such as a fatty acid, alkali metal salt, PEG, and PPG. The absorption promoter is used to solubilize the active. Further, the reference teaches the oral tablet having an enteric coating of carboxymethyl ethyl cellulose and the dissolution of the preparation in the large intestine. JP teaches the dosage form allows the drug to be imported to the blood by remaining intact, without degradation in the upper tract of the digestive system. (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an absorption promoter in the glycyrrhizin preparation since Masanobu teaches it has a solubilizing agent for the active. One would be motivated to do so with the expectation of similar results since Masanobu also teaches a glycyrrhizin preparation that is to be delivered to the lower GI tract.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3-255037 in view of Takada (5,637,319) in further view of Antoku et al (5434142).

As set forth above, JP teaches a glycyrrhizin preparation and Takada teaches an ethylcellulose coated dosage form for delivery to the lower GI tract.

The references do not teach the inclusion of an additional absorption promoter or the amount of active.

Antoku et al teach a method of treating muscular dystrophy with glycyrrhizin. The reference teaches the dose of glycyrrhizin depends on the age and symptoms of the patient but general it is sufficient in the range of 150-225 mg. (col. 2, lines 37-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Antoku et al because the reference teaches the dose range of glycyrrhizin to be sufficient and Antoku et al teaches the amount depends on variable factors such as age and symptoms.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

October 8, 2002

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616